

# Clinical Practice Guideline: Otitis Media with Effusion Executive Summary (Update)

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*Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.*

## Abstract

The American Academy of Otolaryngology—Head and Neck Surgery Foundation has published a supplement to this issue of *Otolaryngology—Head and Neck Surgery* featuring the updated “Clinical Practice Guideline: Otitis Media with Effusion.” To assist in implementing the guideline recommendations, this article summarizes the rationale, purpose, and key action statements. The 18 recommendations developed emphasize diagnostic accuracy, identification of children who are most susceptible to developmental sequelae from otitis media with effusion, and education of clinicians and patients regarding the favorable natural history of most otitis media with effusion and the lack of efficacy for medical therapy (eg, steroids, antihistamines, decongestants). An updated guideline is needed due to new clinical trials, new systematic reviews, and the lack of consumer participation in the initial guideline development group.

## Keywords

otitis media with effusion, middle ear effusion, tympanostomy tubes, adenoidectomy, clinical practice guideline

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## Differences from Prior Guideline

This clinical practice guideline is an update and replacement for a guideline codeveloped in 2004 by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).<sup>1</sup> An update was necessitated by new primary studies and systematic reviews that might suggest a need for modifying clinically important recommendations. Changes in content and methodology from the prior guideline include the following:

- Addition of consumer advocates to the guideline development group

- New evidence from 4 clinical practice guidelines, 20 systematic reviews, and 49 randomized controlled trials (RCTs)
- Emphasis on patient education and shared decision making with an option grid for surgery and new tables of counseling opportunities and frequently asked questions
- Expanded action statement profiles to explicitly state quality improvement opportunities, confidence in the evidence, intentional vagueness, and differences of opinion
- Enhanced external review process to include public comment and journal peer review
- Additional information on pneumatic otoscopy and tympanometry to improve diagnostic certainty for otitis media with effusion (OME)
- Expanded information on speech and language assessment for children with OME
- New recommendations for managing OME in children who fail a newborn hearing screen, evaluating at-risk children for OME, and educating and counseling parents
- A new recommendation against using topical intranasal steroids for treating OME
- A new recommendation against adenoidectomy for a primary indication of OME in children <4 years old, including those with prior tympanostomy tubes, unless a distinct indication exists (nasal obstruction, chronic adenoiditis)
- A new recommendation for assessing OME outcomes by documenting OME resolution, improved hearing, or improved quality of life (QOL)
- New algorithm to clarify decision making and action statement relationships

## Introduction

OME is defined as the presence of fluid in the middle ear (**Table 1**) without signs or symptoms of acute ear infection.<sup>2,3</sup> The condition is common enough to be called an “occupational hazard of early childhood”<sup>4</sup> because about 90% of

**Table 1.** Abbreviations and Definitions of Common Terms.

Term	Definition
Otitis media with effusion (OME) Chronic OME	The presence of fluid in the middle ear without signs or symptoms of acute ear infection. OME persisting for $\geq 3$ months from the date of onset (if known) or from the date of diagnosis (if onset is unknown).
Acute otitis media (AOM) Middle ear effusion	The rapid onset of signs and symptoms of inflammation of the middle ear. Fluid in the middle ear from any cause. Middle ear effusion is present with both OME and AOM and may persist for weeks or months after the signs and symptoms of AOM resolve.
Hearing assessment	A means of gathering information about a child's hearing status, which may include caregiver report, audiologic assessment by an audiologist, or hearing testing by a physician or allied health professional using screening or standard equipment, automated or manual. Does not include use of noisemakers or other nonstandardized methods.
Pneumatic otoscopy	A method of examining the middle ear by using an otoscope with an attached rubber bulb to change the pressure in the ear canal and see how the eardrum reacts. A normal eardrum moves briskly with applied pressure, but when there is fluid in the middle ear, the movement is minimal or sluggish.
Tympanogram	An objective measure of how easily the tympanic membrane vibrates and at what pressure it does so most easily (pressure admittance function). If the middle ear is filled with fluid (eg, OME), vibration is impaired, and the result is a flat or nearly flat tracing; if the middle ear is filled with air but at a higher or lower pressure than the surrounding atmosphere, the peak on the graph will be shifted in position based on the pressure (to the left if negative, to the right if positive).
Conductive hearing loss	Hearing loss from abnormal or impaired sound transmission to the inner ear, which is often associated with effusion in the middle ear, but can be caused by other middle ear abnormalities as tympanic membrane perforation or ossicle abnormalities
Sensorineural hearing loss	Hearing loss that results from abnormal transmission of sound from the sensory cells of the inner ear to the brain.

children have OME before school age<sup>5</sup> and they develop, on average, 4 episodes of OME every year.<sup>6</sup> Synonyms for OME include ear fluid and serous, secretory, or nonsuppurative otitis media.

About 2.2 million diagnosed episodes of OME occur annually in the United States at a cost of \$4.0 billion.<sup>7</sup> The indirect costs are likely much higher since OME is largely asymptomatic and many episodes are therefore undetected, including those episodes in children with hearing difficulties or school performance issues. In contrast, acute otitis media (AOM) is the rapid onset of signs and symptoms of inflammation in the middle ear,<sup>8</sup> most often with ear pain and a bulging eardrum. In lay terms, OME is often called “ear fluid” and AOM “ear infection.”

OME may occur during an upper respiratory infection, spontaneously because of poor eustachian tube function, or as an inflammatory response following AOM, most often between the ages of 6 months and 4 years.<sup>9</sup> In the first year of life, >50% of children will experience OME, increasing to

>60% by age 2 years.<sup>10</sup> When children aged 5 to 6 years in primary school are screened for OME, about 1 in 8 are found to have fluid in one or both ears.<sup>11</sup> The prevalence of OME in children with Down syndrome or cleft palate, however, is much higher, ranging from 60% to 85%.<sup>12,13</sup>

Most episodes of OME resolve spontaneously within 3 months, but about 30% to 40% of children have repeated OME episodes, and 5% to 10% of episodes last  $\geq 1$  year.<sup>2,5,14</sup> Persistent middle ear fluid from OME results in decreased mobility of the tympanic membrane and serves as a barrier to sound conduction.<sup>15</sup> At least 25% of OME episodes persist for  $\geq 3$  months<sup>16</sup> and may be associated with hearing loss, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, recurrent AOM, or reduced QOL.<sup>17</sup> Less often, OME may cause structural damage to the tympanic membrane that requires surgical intervention.<sup>16</sup>

The high prevalence of OME—along with many issues, including difficulties in diagnosis and assessing its duration,

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**Table 2.** Risk Factors for Developmental Difficulties in Children with OME.<sup>a</sup>


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Permanent hearing loss independent of OME
Suspected or confirmed speech and language delay or disorder
Autism spectrum disorder and other pervasive developmental disorders
Syndromes (eg, Down) or craniofacial disorders that include cognitive, speech, or language delays
Blindness or uncorrectable visual impairment
Cleft palate, with or without associated syndrome
Developmental delay

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Abbreviation: OME, otitis media with effusion.

<sup>a</sup>Sensory, physical, cognitive, or behavioral factors that place children who have OME at increased risk for developmental difficulties (delay or disorder).<sup>1</sup>

associated conductive hearing loss, potential impact on child development, and significant practice variations in management—makes OME an important condition for up-to-date clinical practice guidelines.

## Purpose

The purpose of the multidisciplinary guideline is to identify quality improvement opportunities in managing OME and to create explicit and actionable recommendations to implement these opportunities in clinical practice. Specifically, the goals are to improve diagnostic accuracy, identify children who are most susceptible to developmental sequelae from OME (**Table 2**), and educate clinicians and patients regarding the favorable natural history of most OME and the lack of clinical benefits for medical therapy (eg, steroids, antihistamines, decongestants). Additional goals relate to OME surveillance, evaluation of hearing and language, and management of OME detected by newborn screening.

The target patient for the guideline is a child aged 2 months through 12 years with OME, with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae (**Table 2**). The age range was chosen for consistency with the precursor guideline<sup>1</sup> and to correspond with inclusion criteria in many OME studies. The guideline is intended for all clinicians who are likely to diagnose and manage children with OME, and it applies to any setting in which OME would be identified, monitored, or managed. This guideline, however, does not apply to patients <2 months or >12 years old.

The guideline does not explicitly discuss indications for tympanostomy tubes, even though OME is the leading indication for tympanostomy tube insertion, because indications are thoroughly explained in a companion clinical practice guideline from the AAO-HNS.<sup>17</sup> Rather, discussions of surgery focus on adjuvant procedures (eg, adenoidectomy, myringotomy) and sequelae of OME (eg, retraction pockets, atelectasis of the middle ear) that were excluded from the tympanostomy tube guideline.

## Methods

### General Methods and Literature Search

In developing the update of the evidence-based clinical practice guideline, the methods outlined in the AAO-HNSF “Clinical Practice Guideline Development Manual, Third Edition” were followed explicitly.<sup>18</sup>

An executive summary of the original OME guideline<sup>1</sup> was sent to a panel of expert reviewers from the fields of general otolaryngology, pediatric otolaryngology, otology, family practice, pediatrics, nursing, audiology, and speech language pathology who assessed the key action statements to decide if they should be kept in their current form, revised, or removed and to identify new research that might affect the guideline recommendations. The reviewers concluded that the original guideline action statements remained valid but should be updated with major modifications. Suggestions were also made for new key action statements.

An information specialist conducted 2 systematic literature searches using a validated filter strategy to identify clinical practice guidelines, systematic reviews, and RCTs published since the prior guideline (2004). Search terms used were “Otitis Media with Effusion”[Mesh] OR “otitis media with effusion”[tiab] OR (OME[tiab] AND otitis) OR “middle ear effusion”[tiab] OR “glue ear”[tiab]; otitis/exp OR otitis AND media AND (effusion/exp OR effusion); MH “Otitis Media with Effusion” OR TI (OME and effusion) OR TI “otitis media with effusion”; and (DE “OTITIS MEDIA”) OR “otitis media with effusion” OR (OME AND otitis) OR “middle ear effusion” OR “glue ear.” In certain instances, targeted searches for lower-level evidence were performed to address gaps from the systematic searches identified in writing the guideline. The original MEDLINE search was updated from January 2004 to January 2015 to include MEDLINE, National Guidelines Clearinghouse, Cochrane Database of Systematic Reviews, Excerpta Medica database, Cumulative Index to Nursing and Allied Health, and the Allied and Complimentary Medicine Database.

1. The initial search for clinical practice guidelines identified 13 guidelines. Quality criteria for including guidelines were (a) an explicit scope and purpose, (b) multidisciplinary stakeholder involvement, (c) systematic literature review, (d) explicit system for ranking evidence, and (e) explicit system for linking evidence to recommendations. The final data set retained 4 guidelines that met inclusion criteria.
2. The initial search for systematic reviews identified 138 systematic reviews or meta-analyses that were distributed to the panel members. Quality criteria for including reviews were (a) relevance to the guideline topic, (b) clear objective and methodology, (c) explicit

search strategy, and (d) valid data extraction methods. The final data set retained was 20 systematic reviews or meta-analyses that met inclusion criteria.

3. The initial search for RCTs identified 86 RCTs that were distributed to panel members for review. Quality criteria for including RCTs were (a) relevance to the guideline topic, (b) publication in a peer-reviewed journal, and (c) clear methodology with randomized allocation to treatment groups. The total final data set retained 49 RCTs that met inclusion criteria.

The AAO-HNSF assembled a guideline update group (GUG) representing the disciplines of otolaryngology—head and neck surgery, pediatric otolaryngology, otology, pediatrics, allergy and immunology, family medicine, audiology, speech language pathology, advanced practice nursing, and consumer advocacy. The GUG had several conference calls and one in-person meeting, during which they defined the scope and objectives of updating the guideline, reviewed comments from the expert panel review for each key action statement, identified other quality improvement opportunities, and reviewed the literature search results.

The evidence profile for each statement in the earlier guideline was then converted into an expanded action statement profile for consistency with our current development standards.<sup>18</sup> Information was added to the action statement profiles regarding the quality improvement opportunity, level of confidence in the evidence, differences of opinion, intentional vagueness, and any exclusion to which the action statement does not apply. New key action statements were developed with an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. Electronic decision support software (BRIDGE-Wiz, Yale Center for Medical Informatics, New Haven, Connecticut) was used to facilitate creating actionable recommendations and evidence profiles.<sup>19</sup>

The updated guideline then underwent GuideLine Implementability Appraisal to appraise adherence to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation.<sup>20</sup> The GUG received summary appraisals and modified an advanced draft of the guideline based on the appraisal. The final draft of the updated clinical practice guideline was revised based on comments received during multidisciplinary peer review, open public comment, and journal editorial peer review. A scheduled review process will occur 5 years from publication or sooner if new, compelling evidence warrants earlier consideration.

**Classification of Evidence-Based Statements.** Guidelines are intended to reduce inappropriate variations in clinical care, to produce optimal health outcomes for patients, and to minimize harm. The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the *quality of evidence* and the *balance*

*of benefit and harm* that is anticipated when the statement is followed.

Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a strong recommendation than what might be expected with a recommendation. Options offer the most opportunity for practice variability.<sup>21</sup> Clinicians should always act and decide in a way that they believe will best serve their individual patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.<sup>22</sup>

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the GUG sought to minimize harm, diminish unnecessary and inappropriate therapy, and reduce the unnecessary use of systemic antibiotics. A major goal of the panel was to be transparent and explicit about how values were applied and to document the process.

**Financial Disclosure and Conflicts of Interest.** The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the AAO-HNSF. Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call and were updated at each subsequent call and in-person meeting. After review and discussion of these disclosures,<sup>23</sup> the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.<sup>24</sup>

### Guideline Key Action Statements

Each evidence-based statement is organized in a similar fashion: a key action statement in bold, followed by the strength of the recommendation in italics. Each key action statement is followed by an "action statement profile" that explicitly states the quality improvement opportunity (and corresponding National Quality Strategy domain based on the original priorities),<sup>25</sup> aggregate evidence quality, level of confidence in evidence (high, medium, low), benefit, risks, harms, costs, and a benefits-harm assessment. Additionally, there are statements of any value judgments, the role of patient preferences, clarification of any intentional vagueness by the panel, exceptions to the statement, any differences of opinion, and a repeat statement of the strength of the recommendation. An overview of each evidence-based statement in this guideline can be found in **Table 3**.

The role of patient, parent, and/or caregiver preferences in making decisions deserves further clarification. For some statements, where the evidence base demonstrates clear benefit, although the role of patient preference for a range of treatments may not be relevant (eg, intraoperative decision making), clinicians should provide patients with clear and comprehensible information on the benefits. This will facilitate patient understanding and shared decision making, which in turn leads to better patient adherence and outcomes. In cases where evidence is weak or benefits unclear, the practice of shared decision making—again, where the management decision is made by a collaborative effort between the clinician and an informed patient—is extremely useful. Factors related to patient preference include (but are not limited to) absolute benefits (number needed to treat), adverse effects (number needed to harm), cost of drugs or procedures, and frequency and duration of treatment.

## Key Action Statements

**STATEMENT 1a. PNEUMATIC OTOSCOPY: The clinician should document the presence of middle ear effusion with pneumatic otoscopy when diagnosing OME in a child.** *Strong recommendation based on systematic review of diagnostic studies with a preponderance of benefit over harm.*

**STATEMENT 1b. PNEUMATIC OTOSCOPY: The clinician should perform pneumatic otoscopy to assess for OME in a child with otalgia, hearing loss, or both.** *Strong recommendation based on systematic review of diagnostic studies with a preponderance of benefit over harm.*

### Action Statement Profile for Statements

#### 1a and 1b

- Quality improvement opportunity: To improve diagnostic accuracy for OME with a readily available but underutilized means of assessing middle ear status (**Table 4**; National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade A, systematic review of cross-sectional studies with a consistent reference standard
- Level of confidence in evidence: High
- Benefit: Improve diagnostic certainty; reduce false-negative diagnoses caused by effusions that do not have obvious air bubbles or an air-fluid level; reduce false-positive diagnoses that lead to unnecessary tests and costs; readily available equipment; document mobility of the tympanic membrane; efficient; cost-effective
- Risks, harms, costs: Costs of training clinicians in pneumatic otoscopy; false-positive diagnoses from nonintact tympanic membrane; minor procedural discomfort
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Pneumatic otoscopy is underutilized for diagnosing OME, especially in primary care

settings; accurate diagnosis of OME using pneumatic otoscopy is a prerequisite for managing children with OME

- Intentional vagueness: None
- Role of patient preferences: Very limited
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None

**STATEMENT 2. TYMPANOMETRY: Clinicians should obtain tympanometry in children with suspected OME for whom the diagnosis is uncertain after performing (or attempting) pneumatic otoscopy.** *Strong recommendation based on extrapolation of systematic reviews of diagnostic studies with a preponderance of benefit over harm.*

### Action Statement Profile for Statement 2

- Quality improvement opportunity: Improve diagnostic accuracy for OME and raise awareness regarding the value of tympanometry as an objective measure of middle ear status (National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade B, extrapolation from systematic review of cross-sectional studies with a consistent reference standard for tympanometry as a primary diagnostic method
- Level of confidence in evidence: High regarding the value of tympanometry for primary diagnosis; medium regarding the value as an adjunct to pneumatic otoscopy
- Benefit: Improved diagnostic accuracy; confirm a suspected diagnosis of OME; obtain objective information regarding middle ear status; differentiate OME (normal equivalent ear canal volume) vs tympanic membrane perforation (high equivalent ear canal volume); obtain prognostic information on likelihood of timely spontaneous resolution (eg, a flat, or type B, tracing has the poorest prognosis); educational value in confirming pneumatic otoscopy findings
- Risks, harms, costs: Cost; lack of access; equipment calibration and maintenance; misinterpretation of findings
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The individual who performs tympanometry is not specified and could be the clinician or another health professional; whether to use portable or table top tympanometry is at the discretion of the clinician
- Role of patient preferences: Limited
- Exceptions: Patients with recent ear surgery or trauma
- Policy level: Strong recommendation
- Differences of opinion: None

**STATEMENT 3. FAILED NEWBORN HEARING SCREEN: Clinicians should document in the medical**

**Table 3.** Summary of Guideline Key Action Statements.

Statement	Action	Strength
1a. Pneumatic otoscopy	The clinician should document the presence of middle ear effusion with pneumatic otoscopy when diagnosing OME in a child.	Strong recommendation
1b. Pneumatic otoscopy	The clinician should perform pneumatic otoscopy to assess for OME in a child with otalgia, hearing loss, or both.	Strong recommendation
2. Tympanometry	Clinicians should obtain tympanometry in children with suspected OME for whom the diagnosis is uncertain after performing (or attempting) pneumatic otoscopy.	Strong recommendation
3. Failed newborn hearing screen	Clinicians should document in the medical record counseling of parents of infants with OME who fail a newborn hearing screen regarding the importance of follow-up to ensure that hearing is normal when OME resolves and to exclude an underlying sensorineural hearing loss.	Recommendation
4a. Identifying at-risk children	Clinicians should determine if a child with OME is at increased risk for speech, language, or learning problems from middle ear effusion because of baseline sensory, physical, cognitive, or behavioral factors ( <b>Table 2</b> ).	Recommendation
4b. Evaluating at-risk children	Clinicians should evaluate at-risk children ( <b>Table 2</b> ) for OME at the time of diagnosis of an at-risk condition and at 12 to 18 mo of age (if diagnosed as being at risk prior to this time).	Recommendation
5. Screening healthy children	Clinicians should <i>not</i> routinely screen children for OME who are not at risk ( <b>Table 2</b> ) and do not have symptoms that may be attributable to OME, such as hearing difficulties, balance (vestibular) problems, poor school performance, behavioral problems, or ear discomfort.	Recommendation (against)
6. Patient education	Clinicians should educate families of children with OME regarding the natural history of OME, need for follow-up, and the possible sequelae.	Recommendation
7. Watchful waiting	Clinicians should manage the child with OME who is not at risk with watchful waiting for 3 mo from the date of effusion onset (if known) or 3 mo from the date of diagnosis (if onset is unknown).	Strong recommendation
8a. Steroids	Clinicians should recommend against using intranasal steroids or systemic steroids for treating OME.	Strong recommendation (against)
8b. Antibiotics	Clinicians should recommend against using systemic antibiotics for treating OME.	Strong recommendation (against)
8c. Antihistamines or decongestants	Clinicians should recommend against using antihistamines, decongestants, or both for treating OME.	Strong recommendation (against)
9. Hearing test	Clinicians should obtain an age-appropriate hearing test if OME persists for $\geq 3$ mo <i>OR</i> for OME of any duration in an at-risk child.	Recommendation
10. Speech and language	Clinicians should counsel families of children with bilateral OME and documented hearing loss about the potential impact on speech and language development.	Recommendation
11. Surveillance of chronic OME	Clinicians should reevaluate, at 3- to 6-mo intervals, children with chronic OME until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.	Recommendation
12a. Surgery for children <4 y old	Clinicians should recommend tympanostomy tubes when surgery is performed for OME in a <i>child less than 4 years old</i> ; adenoidectomy should not be performed unless a distinct indication (eg, nasal obstruction, chronic adenoiditis) exists other than OME.	Recommendation
12b. Surgery for children $\geq 4$ y old	Clinicians should recommend tympanostomy tubes, adenoidectomy, or both when surgery is performed for OME in a <i>child 4 years old or older</i> .	Recommendation
13. Outcome assessment	When managing a child with OME, clinicians should document in the medical record resolution of OME, improved hearing, or improved quality of life.	Recommendation

Abbreviation: OME, otitis media with effusion.

**record counseling of parents of infants with OME who fail a newborn hearing screen regarding the importance of follow-up to ensure that hearing is normal when OME**

**resolves and to exclude an underlying sensorineural hearing loss (SNHL).** *Recommendation based on observational studies with a predominance of benefit over harm.*

**Table 4.** Practical Tips for Performing Pneumatic Otoscopy.

Pneumatic Otoscopy Tip	Rationale
After attaching the speculum to the otoscope, squeeze the pneumatic bulb fully, then firmly cover the tip of the speculum with your finger and let go of the bulb.	The bulb should stay compressed after blocking the speculum if there are no air leaks; if the bulb opens (eg, the pressure is released), check the speculum for a tight fit and the bulb and tubing for leaks.
Choose a speculum that is slightly wider than the ear canal to obtain an air-tight seal.	A speculum that is too narrow cannot form a proper seal and will give false-positive results.
Before inserting the speculum, squeeze the pneumatic bulb halfway (about 50% of the bulb width), then insert it into the canal.	Squeezing the bulb first allows the examiner to apply both negative pressure (by releasing the bulb) and positive pressure (by further squeezing).
Insert the speculum deep enough into the ear canal to obtain an air-tight seal but not deep enough to cause pain.	Limiting insertion to the cartilaginous (outer) portion of the ear canal is painless, but deep insertion that touches the bony ear canal and periosteum can be very painful.
Examine tympanic membrane mobility by squeezing and releasing the bulb <i>very slightly and very gently</i> several times.	Many children have negative pressure in their middle ear space, so both positive pressure (squeezing the bulb) and negative (releasing the bulb) pressure are needed to fully assess mobility. Using slight and gentle pressure will avoid unnecessary pain.
Diagnose OME when movement of the tympanic membrane is sluggish, dampened, or restricted; complete absence of mobility is not required.	When OME is absent, the tympanic membrane will move briskly with minimal pressure. Motion is reduced substantially with OME, but with enough pressure some motion is almost always possible.

Abbreviation: OME, otitis media with effusion.

### Action Statement Profile for Statement 3

- Quality improvement opportunity: Increase adherence to follow-up and ensure that an underlying SNHL is not missed (National Quality Strategy domains: care coordination, patient and family engagement)
- Aggregate evidence quality: Grade C, indirect observational evidence on the benefits of longitudinal follow-up for effusions in newborn screening programs and the prevalence of SNHL in newborn screening failures with OME
- Level of confidence in evidence: Medium
- Benefit: More prompt diagnosis of SNHL; earlier intervention for hearing loss; reduce loss to follow-up; reassure parents
- Risks, harms, costs: Time spent in counseling; parental anxiety from increased focus on child hearing issues
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The method and specifics of follow-up are at the discretion of the clinician but should seek resolution of OME within 3 months of onset, or, if not known, diagnosis
- Role of patient preferences: Minimal role regarding the need for counseling but a large role for shared decision making in the specifics of how follow-up is implemented and in what specific care settings
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

### STATEMENT 4a. IDENTIFYING AT-RISK CHILDREN: Clinicians should determine if a child with OME is at

increased risk for speech, language, or learning problems from middle ear effusion because of baseline sensory, physical, cognitive, or behavioral factors (Table 2). *Recommendation based on observational studies with a preponderance of benefit over harm.*

**STATEMENT 4b. EVALUATING AT-RISK CHILDREN: Clinicians should evaluate at-risk children (Table 2) for OME at the time of diagnosis of an at-risk condition and at 12 to 18 months of age (if diagnosed as being at risk prior to this time).** *Recommendation based on observational studies with a preponderance of benefit over harm.*

### Action Statement Profile for Statements 4a and 4b

- Quality improvement opportunity: Raise awareness of a subset of children with OME (Table 2) who are disproportionately affected by middle ear effusion as compared with otherwise healthy children and to detect OME in at-risk children that might have been missed without explicit screening but could affect their developmental progress (National Quality Strategy domain: population/public health)
- Aggregate evidence quality: Grade C, observational studies regarding the high prevalence of OME in at-risk children and the known impact of hearing loss on child development; D, expert opinion on the ability of prompt diagnosis to alter outcomes
- Level of confidence in the evidence: Medium
- Benefit: Identify at-risk children who might benefit from early intervention for OME (including tympanostomy tubes) and from more active and accurate surveillance of middle ear status; identify unsus-

pected OME and reduce the impact of OME and associated hearing loss on child development

- **Risks, harms, costs:** Direct costs of evaluating for OME (eg, tympanometry), identifying self-limited effusions, parental anxiety, potential for overtreatment
- **Benefit-harm assessment:** Preponderance of benefit
- **Value judgments:** The GUG assumed that at-risk children (**Table 2**) are less likely to tolerate OME than would the otherwise healthy child and that persistent OME could limit the benefit of ongoing therapies and education interventions for at-risk children with special needs; assumption that early identification of OME in at-risk children could improve developmental outcomes
- **Intentional vagueness:** The method of evaluating for OME is not specified but should follow recommendations in this guideline regarding pneumatic otoscopy and tympanometry; a time interval of 12 to 18 months is stated to give the clinician flexibility and to ensure that evaluation takes place at a critical time in the child's development
- **Role of patient preferences:** None
- **Exceptions:** None
- **Policy level:** Recommendation
- **Differences of opinion:** None

**STATEMENT 5. SCREENING HEALTHY CHILDREN: Clinicians should not routinely screen children for OME who are not at risk and do not have symptoms that may be attributable to OME, such as hearing difficulties, balance (vestibular) problems, poor school performance, behavioral problems, or ear discomfort.** *Recommendation against based on RCTs and cohort studies with a preponderance of harm over benefit.*

#### Action Statement Profile for Statement 5

- **Quality improvement opportunity:** Avoid unnecessary tests and treatment for a highly prevalent and usually self-limited condition (National Quality Strategy domains: efficient use of health care resources, population/public health)
- **Aggregate evidence quality:** Grade A, systematic review of RCTs
- **Level of confidence in the evidence:** High
- **Benefit:** Avoid unnecessary tests, avoid unnecessary treatment, limit parent anxiety
- **Risks, harms, costs:** Potential to miss clinically relevant OME in some children
- **Benefit-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** None
- **Role of patient preferences:** Limited, but a parent can request screening if desired
- **Intentional vagueness:** The word “routine” is used to indicate that there may be specific circumstances where screening is appropriate—for example, a child with a strong family history of otitis media or a child

who is suspected to be at risk but does not yet have a formal at-risk diagnosis

- **Exceptions:** None
- **Policy level:** Recommendation against
- **Difference of opinions:** None

**STATEMENT 6. PATIENT EDUCATION: Clinicians should educate families of children with OME regarding the natural history of OME, the need for follow-up, and the possible sequelae.** *Recommendation based on observational studies and preponderance of benefit over harm.*

#### Action Statement Profile for Statement 6

- **Quality improvement opportunity:** Provide clear, patient-friendly education regarding OME, its natural history, and possible sequelae to empower families for shared decisions (**Table 5**; National Quality Strategy domain: patient and family engagement)
- **Aggregate evidence quality:** Grade C, observational studies
- **Level of confidence in the evidence:** High
- **Benefits:** Reduce anxiety; facilitate shared decisions; provide parents with a fuller understanding of their child's condition; emphasize the importance of follow-up; educate families about risk factors and coping strategies
- **Risks, harms, costs:** Time for education
- **Benefit-harm assessment:** Preponderance of benefit over harm
- **Value judgments:** None
- **Intentional vagueness:** None
- **Role of patient preferences:** Limited
- **Exceptions:** None
- **Policy level:** Recommendation
- **Differences of opinion:** None

**STATEMENT 7. WATCHFUL WAITING: Clinicians should manage the child with OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or 3 months from the date of diagnosis (if onset is unknown).** *Strong recommendation based on systematic review of cohort studies and preponderance of benefit over harm.*

#### Action Statement Profile for Statement 7

- **Quality improvement opportunity:** Avoid interventions with potential adverse events and cost for a condition that is usually self-limited (National Quality Strategy domains: patient safety, efficient use of health care resources)
- **Aggregate evidence quality:** Grade A, systematic review of cohort studies
- **Level of confidence in the evidence:** High
- **Benefit:** Avoid unnecessary referrals, evaluations, and interventions; take advantage of favorable natural history
- **Risks, harms, costs:** Delays in therapy for OME that persists >3 months, prolongation of hearing loss

**Table 5.** Frequently Asked Questions: Treating and Managing Ear Fluid.

Question	Answer
What is ear fluid?	Ear fluid, also called otitis media with effusion, is a buildup of mucus or liquid behind the ear drum without symptoms of infection.
Is it possible that the ear fluid will just go away on its own?	Fluid often goes away on its own, so your doctor will often recommend watchful waiting for the first 3 mo. Be sure to follow-up with your doctor to make sure the fluid goes away completely
Does it matter how long the fluid has been there?	The fluid is most likely to go away quickly if it has been there <3 mo or has a known start time, such as after a cold or ear infection. Fluid is much more likely to persist when it has been there for at least 3 mo or when it is found during a regular checkup visit and the start date is unknown.
How might the ear fluid affect my child?	The most common symptoms of ear fluid are mild discomfort, fullness in the ear, and mild hearing problems. Some children also have disturbed sleep, emotional distress, delayed speech, irritability, clumsiness, balance problems, or trouble learning in school.
What can I do at home to help the fluid go away?	Keep your child away from secondhand smoke, especially in closed spaces, such as the car or in the house. If your child is >12 mo old and still uses a pacifier, stopping the pacifier in the daytime may help the fluid go away.
Will medications or other therapies help the fluid go away?	Medical treatment does not work well, so you should <i>not</i> give your child antibiotics, antihistamines, decongestants, steroids (by mouth or in the nose), or drugs to reduce acid reflux. No benefits have ever been shown for chiropractic, special diets, herbal remedies, complementary medicine, or alternative (natural) therapies.
Do I still need to follow up with my doctor, even if my child seems fine?	Yes, because the fluid may still be there and could later cause problems. Fluid that lasts a long time can damage the ear and require surgery. Also, young children often do not express themselves well, even when struggling with hearing problems or other issues related to the fluid. The best way to prevent problems is to see the doctor every 3 to 6 mo until the fluid goes away.
Does the fluid cause hearing loss?	The fluid can make it harder for your child to hear, especially in a group setting or with background noise, but the effect is usually small and goes away when the fluid clears up.
How can I help my child hear better?	Stand or sit close to your child when you speak and be sure to let him or her see your face. Speak very clearly, and if your child does not understand something, repeat it. Hearing difficulties can be frustrating for your child, so be patient and understanding.
Will the fluid turn into an ear infection?	The fluid cannot directly turn into an ear infection, but during a cold, it increases your child's risk of getting an ear infection because the fluid makes it easier for germs to grow and spread.
Can my child travel by airplane if ear fluid is present?	If the ear is completely full of fluid, there is usually no problem, but when the fluid is partial or mixed with air, it can hurt when the plane is coming down. Your doctor can measure the amount of fluid with a tympanogram, which gives a flat reading when the ear is full. It may help to keep your child awake when the plane is landing and encourage him or her to swallow to even out the pressure.

- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of avoiding interventions in an often self-limited condition
- Intentional vagueness: None
- Role of patient preferences: Small
- Exceptions: At-risk children (**Table 2**), who may be offered tympanostomy tubes earlier than 3 months if there is a type B tympanogram in one or both ears
- Policy level: Strong recommendation
- Differences of opinion: None

**STATEMENT 8a. STEROIDS: Clinicians should recommend against using intranasal steroids or systemic steroids for treating OME.** *Strong recommendation against based on systematic review of RCTs and preponderance of harm over benefit.*

**STATEMENT 8b. ANTIBIOTICS: Clinicians should recommend against using systemic antibiotics for treating OME.** *Strong recommendation against based on systematic review of RCTs and preponderance of harm over benefit.*

**STATEMENT 8c. ANTIHISTAMINES OR DECONGESTANTS: Clinicians should recommend against using antihistamines, decongestants, or both for treating OME.** *Strong recommendation against based on systematic review of RCTs and preponderance of harm over benefit.*

#### *Action Statement Profile for Statements 8a, 8b, and 8c*

- Quality improvement opportunity: Discourage medical therapy that does not affect long-term outcomes for OME (resolution, hearing levels, or need for tym-

panostomy tubes) but does have significant cost and potential adverse events (National Quality Strategy domain: patient safety, efficient use of health care resources)

- Aggregate evidence quality: Grade A, systematic review of well-designed RCTs
- Level of confidence in the evidence: High
- Benefit: Avoid side effects and reduce cost by not administering medications; avoid delays in definitive therapy caused by short-term improvement, then relapse; avoid societal impact of inappropriate antibiotic prescribing on bacterial resistance and transmission of resistant pathogens
- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit over harm (in recommending against therapy)
- Value judgments: Emphasis on long-term outcomes, based on high-quality systematic reviews, even though some therapies (eg, antibiotics, systemic steroids) have documented short-term benefits
- Intentional vagueness: None
- Role of patient preferences: Small
- Exceptions: Patients in whom any of these medications are indicated for primary management of a coexisting condition with OME
- Policy level: Strong recommendation (against therapy)
- Differences of opinion: None

**STATEMENT 9. HEARING TEST: Clinicians should obtain an age-appropriate hearing test if OME persists for  $\geq 3$  months OR for OME of any duration in an at-risk child.** *Recommendation based on cohort studies and preponderance of benefit over harm.*

#### Action Statement Profile for Statement 9

- Quality improvement opportunity: Obtains objective information on hearing status that could influence counseling and management of OME (National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade C, systematic review of RCTs showing hearing loss in about 50% of children with OME and improved hearing after tympanostomy tube insertion; observational studies showing an impact of hearing loss associated with OME on children's auditory and language skills
- Level of confidence in the evidence: Medium
- Benefit: Detect unsuspected hearing loss; quantify the severity and laterality of hearing loss to assist in management and follow-up decisions; identify children who are candidates for tympanostomy tubes
- Risks, harms, costs: Access to audiology, cost of the audiology assessment
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Knowledge of hearing status is important for counseling and managing children with

OME and optimizing their learning environment, even if this information does not determine surgical candidacy

- Intentional vagueness: The words *age-appropriate* audiologic testing are used to recognize that the specific methods will vary with the age of the child, but a full discussion of the specifics of testing is beyond the scope of this guideline
- Role of patient preferences: Small; caregivers may decline testing
- Exceptions: None
- Policy level: Recommendation
- Difference of opinion: None

**STATEMENT 10. SPEECH AND LANGUAGE: Clinicians should counsel families of children with bilateral OME and documented hearing loss about the potential impact on speech and language development.** *Recommendation based on observational studies and preponderance of benefit over harm.*

#### Action Statement Profile for Statement 10

- Quality improvement opportunity: Raise awareness of the potential impact of hearing loss secondary to OME on a child's speech and language and facilitate caregiver education (National Quality Strategy domains: patient and family engagement, care coordination)
- Aggregate evidence quality: Grade C, observational studies; extrapolation of studies regarding the impact of permanent mild hearing loss on child speech and language
- Level of confidence in the evidence: Medium
- Benefit: Raise awareness among clinicians and caregivers; educate caregivers; identify and prioritize at-risk children for additional assessment
- Risks, harms, costs: Time spent in counseling
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Group consensus that there is likely an underappreciation of the impact of bilateral hearing loss secondary to OME on speech and language development
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Difference of opinion: None

**STATEMENT 11. SURVEILLANCE OF CHRONIC OME: Clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.** *Recommendation based on observational studies with a preponderance of benefit over harm.*

### Action Statement Profile for Statement 11

- Quality improvement opportunity: Emphasize that regular follow-up is an important aspect of managing chronic OME that can help avoid sequelae by identifying children who develop signs or symptoms that would prompt intervention (National Quality Strategy domains: patient safety, clinical process/effectiveness)
- Aggregate evidence quality: Grade C, observational studies
- Level of confidence in the evidence: High
- Benefit: Detection of structural changes in the tympanic membrane that may require intervention; detection of new hearing difficulties or symptoms that would lead to reassessing the need for intervention, including tympanostomy tubes; discussion of strategies for optimizing the listening-learning environment for children with OME; as well as ongoing counseling and education of parents/caregiver
- Risks, harms, costs: Cost of follow-up
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Although it is uncommon, untreated OME can cause progressive changes in the tympanic membrane that require surgical intervention. There was an implicit assumption that surveillance and early detection/intervention could prevent complications and would also provide opportunities for ongoing education and counseling of caregivers.
- Intentional vagueness: The surveillance interval is broadly defined at 3 to 6 months to accommodate provider and patient preference; “significant” hearing loss is broadly defined as one that is noticed by the caregiver, is reported by the child, or interferes in school performance or QOL
- Role of patient preferences: Moderate; opportunity for shared decision making regarding the surveillance interval
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

**STATEMENT 12a. SURGERY FOR CHILDREN <4 YEARS OLD: Clinicians should recommend tympanostomy tubes when surgery is performed for OME in a child <4 years old; adenoidectomy should not be performed unless a distinct indication (eg, nasal obstruction, chronic adenoiditis) exists other than OME.** *Recommendation based on systematic reviews of RCTs with a preponderance of benefit over harm.*

**STATEMENT 12b: SURGERY FOR CHILDREN AGE ≥4 YEARS OLD: Clinicians should recommend tympanostomy tubes, adenoidectomy, or both when surgery is performed for OME in a child aged 4 years or older.** *Recommendation based on systematic reviews of RCTs and observational studies with a preponderance of benefit over harm.*

### Action Statement Profile for Statements 12a and 12b

- Quality improvement opportunity: Promote effective therapy for OME (tubes at all ages; adenoidectomy age ≥4 years) and discourage therapy with limited or no benefits (adenoidectomy age <4 years) (National Quality Strategy domains: patient safety, clinical process/effectiveness)
- Aggregate evidence quality: Grade B, systematic review of RCTs (tubes, adenoidectomy) and observational studies (adenoidectomy)
- Level of confidence in the evidence: Medium, because of limited data on long-term benefits of these interventions and heterogeneity among RCTs included in the systematic reviews
- Benefit: promoting effective therapy; avoiding adenoidectomy in an age group where benefits have not been shown as a primary intervention for OME; benefits of surgery that include improved hearing, reduced prevalence of OME, and less need for additional tympanostomy tube insertion (after adenoidectomy)
- Risks, harms, costs: Risks of anesthesia and specific surgical procedures, sequelae of tympanostomy tubes and adenoidectomy
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Although some studies suggest benefits of adenoidectomy for children <4 years old as primary therapy for OME, the data are inconsistent and relatively sparse; the additional surgical risks of adenoidectomy (eg, velopharyngeal insufficiency, more complex anesthesia) were felt to outweigh the uncertain benefits in this group
- Intentional vagueness: For children ≥4 years old, the decision to offer tympanostomy tubes, adenoidectomy, or both is based on shared decision making
- Role of patient preferences (Table 6): Moderate role in the choice of surgical procedure for children ≥4 years old (tubes, adenoidectomy, or both)
- Exceptions: Adenoidectomy may be contraindicated in children with cleft palate or syndromes associated with a risk of velopharyngeal insufficiency
- Policy level: Recommendation
- Difference of opinion: None

**STATEMENT 13. OUTCOME ASSESSMENT: When managing a child with OME, clinicians should document in the medical record resolution of OME, improved hearing, or improved QOL.** *Recommendation based on RCTs and cohort studies with a preponderance of benefit over harm.*

### Action Statement Profile for Statement 13

- Quality improvement opportunity: Focus on patient-centered outcome assessment when managing children with OME (National Quality Strategy domain: clinical process/effectiveness)

**Table 6.** Shared Decision Grid for Parents and Caregivers regarding Surgical Options for Otitis Media with Effusion.<sup>a</sup>

Frequently Asked Questions	Watchful Waiting (Surveillance)	Ear (Tympanostomy) Tube Placement	Adenoidectomy
Are there any age restrictions?	Watchful waiting can be done at any age	Ear tubes can be done at any age	Adenoidectomy is not recommended below age 4 y for treating ear fluid that persists for at least 3 mo
What does it involve?	Checking the eardrum every 3 to 6 mo in your doctor's office. Periodic hearing tests may also be performed.	Placing a tiny tube in the eardrum to reduce fluid buildup that causes hearing loss, then checking the tube in your doctor's office until it falls out.	Removing most of the adenoids, a clump of tissue in the back of the nose that stores germs, then checking the ears in your doctor's office to be sure the ear fluid is gone.
How long does the treatment take?	Regular checkups until the fluid in the middle ear goes away (months to years).	The operation takes about 10 to 20 min and usually requires general anesthesia.	The operation takes about 30 min and requires general anesthesia.
How long does it take to recover?	Does not apply.	A few hours.	About 1 or 2 days.
What are the benefits?	Gives your child a chance to recover on his/her own.	Relieves fluid and hearing loss promptly and prevents relapse of fluid while the tube is in place and stays open.	Reduces time with fluid in the future, reduces the need for future ear surgery. Relieves nasal blockage and infections (if applicable).
What are the potential risks and side effects?	Persistent fluid can reduce hearing, bother your child, and can rarely damage the eardrum and cause it to collapse. If the fluid does not eventually go away on its own then watchful waiting could delay more effective treatments.	About 1 in 4 children get an ear infection (drainage) that is treated with eardrops. About 2 or 3 in 100 children have a tiny hole in the eardrum that does not close after the tube falls out and may need surgery. There is a very small risk of serious problems from the anesthesia.	There is a small chance of bleeding (that could require a visit to the office or hospital), infection (that is treated with antibiotics), or delayed recovery. There is a very small risk of abnormal voice (too much air through the nose) or serious problems from the anesthesia.
What usually happens in the long term?	The fluid and hearing loss eventually go away or another treatment is tried.	Most tubes fall out in about 12 to 18 mo. About 1 in every 4 children may need to have them replaced.	The chance that your child may need future ear tubes is reduced by about 50% after adenoidectomy.
Are there any special precautions?	Baths and swimming are fine. Air travel can result in ear pain or damage to the eardrum depending on how much fluid is present.	Baths, swimming, and air travel are fine. Some children need earplugs if water bothers their ears in the bathtub (with head dunking), when diving (>6 ft underwater), or when swimming in lakes or dirty water.	Baths and swimming are fine. Air travel can result in ear pain or damage to the eardrum depending on how much fluid is present.

<sup>a</sup>Adapted from Calkins and colleagues.<sup>26</sup>

- Aggregate evidence quality: Grade C, RCTs and before-and-after studies showing resolution, improved hearing, or improved QOL after management of OME
- Level of confidence in the evidence: High
- Benefit: Document favorable outcomes in management
- Risks, harms, costs: Cost of follow-up visits and audiometry; administrative burden for QOL surveys
- Benefit-harm assessment: Predominance of benefit over harm
- Value judgments: None
- Intentional vagueness: The time frame for assessing outcome is not stated; the method of demonstrating OME resolution (otoscopy or tympanometry) is at the discretion of the clinician

- Role of patient preferences: Small
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

### Disclaimer

The clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing children with otitis media with effusion. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not

absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology—Head and Neck Surgery Foundation emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

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